

REMARKS

In the Office Action, claims 1-25 are rejected under 35 U.S.C. §103. More specifically, claims 1, 3, 4, 8, 14-17, 19 and 20 are rejected in view of PCT Publication No. WO 98/21953 (Nash); claims 5-7, 9, 10, 13, and 22 are rejected in view of Nash and further in view of U.S. Patent Publication No. H1620 (Dolan) and Myers et al.; and claims 2, 12, and 18 are rejected in view of Dolan and further in view of U.S. Patent No. 6,124,258 (Sakurai) and U.S. Patent No. 4,303,580 (Hidalgo). Applicants believe that the obviousness rejections are improper based on at least the reasons set forth below.

With respect to claims 1, 3, 4, 8, 14-17, 19 and 20, the Patent Office alleges that Nash on its own renders obvious the claimed invention as defined by these claims. Applicants believe that Nash is distinguishable from the claimed invention for a number of reasons.

Of pending claims 1, 3, 4, 8, 14-17, 19 and 20, claims 1, 3, 8, 14, and 20 are the sole independent claims. Claim 1 recites an iron fortification system suitable for foods and beverages; claim 3 recites a beverage which is fortified with iron wherein the beverage contains a fortification system; claim 8 recites a retorted liquid beverage which contains lipid and a stable iron fortification system; and claim 20 recites a food containing a fortification system. As claimed, the fortification system includes a ferric-caseinate complex that is obtainable by dissolving a casein source in an aqueous liquid to provide a casein solution; adjusting the pH of the casein solution to about 5.4 to about 6.2; dissolving a ferric salt in an aqueous liquid to provide a ferric solution; adjusting the pH of the ferric solution to about 5.4 to about 6.2; combining the ferric solution with the casein solution and adjusting the pH to about 5.4 to about 7.0; and collecting ferric-caseinate complex. Claim 14 recites a process for the preparation of the ferric-caseinate complex.

The present invention provides an iron fortification system that is suitable for foods and beverages. The fortification system is a ferric-caseinate complex that is stable but in which the iron remains bioavailable. In this regard, the complex is obtained by a specific process that includes combining a ferric salt and a casein solution at specific pH values such that effectively no ferric hydroxide is produced while at the same time caseinate is not precipitated. The resulting iron complexes have a reduced ability to cause deleterious effects, such as lipid oxidation, color degradation, and vitamin C degradation. This makes the iron complexes an ideal vehicle for fortifying foods and beverages. See, specification, p.4, lines 22-29.

In contrast, Applicants believe that Nash is distinguishable from the claimed invention. At the outset, Nash merely provides a recipe for a liquid supplement in which insoluble ferric-orthophosphate is stabilized by a stabilizer and thus fails to describe a ferric-caseinate complex as claimed. As disclosed in Nash, a liquid nutritional supplement is provided with concentrations of a number of different and recommended macro-nutrients and micro-nutrients where iron is disclosed as one of many types of micronutrients that can be used. See, Nash, p. 6, lines 23-27.

The iron is suspended in the form of a water insoluble ferric-orthophosphate and remains in suspension by use of a stabilizer, most preferably kappa-carrageenan. See Nash, page 11, lines 21-22. In contrast, the claimed ferric-caseinate complex is obtained by combining a ferric ion source and a caseinate source in solution at a defined pH as claimed. An example of the ferric-caseinate complex as claimed is provided in Example 1 of the specification on page 7. Further, Applicants have demonstrated that the bioavailability of the ferric-caseinate complex as claimed is very good. See, specification, pages 9-12. For at least these reasons, Applicants believe that Nash is distinguishable from the claimed invention and thus respectfully submit that Nash on its own fails to render obvious the claimed invention.

With respect to claims 5-7, 9, 10, 13, and 22, the Patent Office alleges that Nash in combination with Dolan and Myers et al. renders obvious the claimed invention as defined by these claims. Of these claims, claims 5-7 depend from claim 3; claim 9 depends from claim 8; and claim 22 depends from claim 20.

Claim 10 recites a retorted liquid beverage that contains polyphenols and a stable iron fortification system that includes a ferric-caseinate complex. Claim 13 depends from claim 12 that recites a beverage powder that contains a lipid and an iron fortification system that includes a ferric-caseinate complex. Claim 13 further recites that the beverage powder contains chocolate. As claimed, the complex is obtained by dissolving a casein source in an aqueous liquid to provide a casein solution; adjusting the pH of the casein solution to about 5.4 to about 6.2; dissolving a ferric salt in an aqueous liquid to provide a ferric solution; adjusting the pH of the ferric solution to about 5.4 to about 6.2; combining the ferric solution with the casein solution and adjusting the pH to about 5.4 to about 7.0; and collecting the ferric-caseinate complex. Thus, Applicants believe that claims 5-7, 9, 10, 13, and 22 are distinguishable from Nash on its own at least for substantially the same reasons as discussed above.

Further, Applicants do not believe that the Patent Office can rely solely on Dolan and Myers to remedy the deficiencies of Nash. Indeed, the Patent Office merely relies on Dolan for its alleged teaching regarding a chocolate flavored beverage mix that contains iron and on Myers et al. for its alleged teaching that chocolate is known to contain polyphenols. See, Office Action, page 3. Therefore, Applicants do not believe that Nash, Dolan and Myers et al. even if combinable can be properly modified to cover the claimed invention.

With respect to claims 2, 12, and 18, the Patent Office alleges that Dolan in view of Sakurai and Hidalgo render obvious the claimed invention. Claim 2 depends from claim 1 that recites an iron fortification system as previously discussed; Claim 12 recites a beverage powder as previously discussed; and claim 18 depends from claim 14 that recites a process for the preparation of a ferric-caseinate complex as previously discussed. Applicants believe that Dolan, Sakurai and Hidalgo even if combinable are distinguishable from the claimed invention.

At the outset, the primary Dolan reference fails to describe an iron fortification system, let alone an iron fortification system that includes a ferric-caseinate complex as claimed. Dolan merely describes a flavored chocolate beverage mix, particularly a dry beverage mix that contain a number of ingredients, such as cocoa, protein and additional nutritional supplemental amounts of vitamins and minerals. See, Dolan, Abstract. Moreover, nowhere does Dolan even mention what specific type of iron has to be taken and how much of the specific iron should be used, let alone the pH dependent preparation of a ferric-caseinate complex. Thus, Dolan on its own is clearly distinguishable from the claimed invention.

Further, Applicants do not believe that the Patent Office can rely solely on Sakurai and Hidalgo in support of Dolan. At the outset, Applicants believe that Sakurai should be removed as prior art. In this regard the earliest effective prior art date of Sakurai is July 14, 1999 where the earliest effective filing date for the present application is March 1, 1999 based on an early-filed provisional and parent application having serial No. 60/122,288. Thus, the earliest effective filing date of the present application predates the earliest effective prior art date of Sakurai. Therefore, Sakurai should be precluded as prior art and thus the obviousness rejection in view of Dolan, Sakurai and Hidalgo should be withdrawn for at least this reason.

Even assuming that Sakurai can be considered prior art, Applicants do not believe that Sakurai and Hidalgo can remedy the deficiencies of Dolan. For example, both references fail to disclose or suggest the ferric-caseinate complex that is obtainable as claimed. As disclosed in

Sakurai, the iron-casein complexes are produced by mixing a solution that contains carbonic acid, hydrocarbonic acid or a mixture thereof, a solution that contains iron and a solution that contains caseins. See, Sakurai, Abstract. Clearly, this suggests that carbonic acid and/or hydrocarbonic acid are essential ingredients for the preparation of the complex according to Sakurai. This further suggests that these essential ingredients are participating in the formation of the complexes and thus will be present therein, such as a complex ligand or in association with the complex. Moreover, Sakurai does not mention a water insoluble ferric-caseinate complex product as claimed, but rather a soluble product in solution as disclosed throughout Sakurai, such as Examples 1-3.

With respect to Hildago, the focus of this reference relates to metal caseinates, particularly, caseinates of oligo-elements, such as chromium, cobalt, iron, and the like. See, Hildago, Abstract. The caseinates are prepared from casein by ion exchange in order to introduce the oligo-element. The oligo-element caseinate intermediate product or products may be redissolved and subjected to further processing. See, Hildago, col. 3, lines 3-7. The caseinates of copper and iron may be used in infant and dietetic products. Moreover, Hildago provides ferrous (Fe (II)) or ferric (Fe(III)) caseinate products and also suggests that mixed products may be encountered having Fe(II) and Fe(III) oxidation status and thus fails to recognize the necessity of having the Fe(III) state in contrast to the ferric-caseinate complex as claimed. See, Hildago, col. 1, Table; and col. 1, line 64 to col. 2, line 3. Therefore, even if combinable, Applicants do not believe that one skilled in the art would be inclined to modify the cited art to arrive at the claimed invention.

Based on at least these reasons, Applicants believe that the cited art fails to disclose or suggest the claimed invention. Therefore, Applicants respectfully submit that the cited art, even if combinable, fails to render obvious the claimed invention.

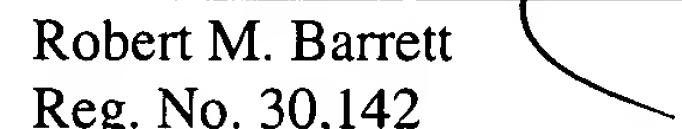
Accordingly, Applicants respectfully request that the obviousness rejections be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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